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Pratteln, 10 June 2022

Re: Posting of Study Results on EUdRACT

EudraCT numbers: 2016-000602-10 (SIDEROS)

Protocol title: 2017-004279-30 (SIDEROS-E), VHP1232 (VHP2018009)
SNT-III-012 (SIDEROS)
A Phase III Double-blind, Randomized, Placebo-Controlled Study assessing the Efficacy, Safety and Tolerability of Idebenone in Patients with Duchenne Muscular Dystrophy Receiving Glucocorticoid Steroids

Sponsor SNT-III-012-E (SIDEROS-E)
A Phase III Open-Label Extension Study to Assess the Long-Term Safety and Efficacy of Idebenone in Patients with Duchenne Muscular Dystrophy (DMD) who completed the SIDEROS study
Santhera Pharmaceuticals (Switzerland) Ltd

Dear Sir or Madam,

The SIDEROS study has been discontinued in October 2020, since data from an interim analysis conducted by an independent DSMB concluded that the study was unlikely to meet its primary endpoint. LPLV date for SIDEROS and SIDEROS-E was 1 December 2020 and 25 November 2020 respectively.

The strategy for the data analysis and results publication are currently being finalised by Santhera, with the final joint abbreviated CSR anticipated by end of September 2022.

Accordingly, posting of results for SIDEROS and SIDEROS-E on EudraCT and other applicable registries will be conducted in a timely manner once the joint abbreviated CSR is available.

Yours sincerely,

Shabir Hasham
Chief Medical Officer
On behalf of Santhera Pharmaceuticals (Switzerland) Ltd